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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,274	05/31/2005	Ryozo Nagai	P26087	6408

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EXAMINER	
HOLLOMAN, NANNETTE	
ART UNIT	PAPER NUMBER
4131	

NOTIFICATION DATE	DELIVERY MODE
02/29/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/511,274	NAGAI ET AL.	
	Examiner	Art Unit	
	NANNETTE HOLLOMAN	4131	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE _3_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) _1- 12_ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) _1-12_ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20060421*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-12 are pending and are the subject of this Office Action. This is the first Office Action on the merits of the Claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim(s) 1, 6, 8, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim(s) 1, 6, 8, 9, and 10 are directed to, "**any agent for controlling any action of a retinoid**." It is well known in the art that retinoids have many actions, for example, implication for treatment of ocular cancer, proliferation of HL-60 cells, interconversions of all trans- and 11-cis retinyl esters in chicken retinas, and inhibits angiotensin II of vascular smooth muscle (VSMC). Therefore, the genus as claimed is highly variable. The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus.

A representative number of species means that the species which are adequately described are representative of the entire genus. The written description

requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, disclosure of drawings, or by disclosure of relevant identifying characteristics, for example, structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus.

Claim(s) 1, 6, 8, 9, and 10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification fails to provide any additional representative species of the claimed genus to show that applicant was in possession of the claimed genus of "an agent for controlling any action of a retinoid", and therefore, it fails to meet the enablement requirement that the specification describe how to make and how to use the invention. There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is undue. These factors include, but are not limited to: Quantity of experimentation necessary, State of the prior art and Relative skill of those in the art, Predictability or unpredictability of the art and Breadth of the claims (see *In re Wands, 858 F.2d at 737, 8 UPQ2d at 1404 (Fed. Cir. 1988))*.

The amount of experimentation required to practice the claimed invention is undue as the claims encompass an unspecified amount of agents for controlling an unspecified amount of actions of retinoid. The specification does not provide support for the broad scope of the claim, which encompasses an unspecified amount of agents for controlling an unspecified amount of actions of retinoid.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1-4, 6-8 and 12 are rejected under 35 U.S.C. 102(b) as being anticipated by Brown et al. (2000). Brown et al. teaches the use of medicament for preventing and/or treating vascular disease, wherein the medicaments include as an active ingredient a substance which is selected from a set comprising retinoid and regulators of retinoid action, and which substantially does not act to suppress the proliferation of vascular endothelial cells and substantially does act to suppress the proliferation of vascular smooth muscle cells (claims 1 and 4). Brown et al. also teaches the use wherein the injury is due to atherosclerosis. Brown et al. also further teaches inclusion of such medicaments in stents or the like in sustained release form in order to prevent vascular restenosis by means of intravascular stents (claim 5).

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Haxsen et al. (2000). Haxsen et al. teaches retinoids inhibit the actions of aniotensin II which is known to promote cell growth of vascular smooth muscle cells and cause arteriosclerosis (p. 637). Haxsen et al. also teaches the use of medicament for preventing and/or treating vascular disease, wherein the medicaments include as an active ingredient a substance which is selected from a set comprising retinoids and regulators of retinoid action, and which substantially does not act to suppress the proliferation of vascular endothelial cells and substantially does act to suppress the proliferation of vascular smooth muscle cells.

Claim(s) 9 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Zhou et al. (1995). Zhou et al. teaches the use of retinoids in the prevention and/or treatment of cardiac hypertrophy (p. 7391).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim(s) 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. as applied to claim(s) 1-4, 6-8 and 12 above, and further in view of Kagechika et al. (1988). Brown et al. teaches the use of medicament for preventing and/or treating vascular disease, wherein the medicaments include as an active

ingredient a substance which is selected from a set comprising retinoids and regulators of retinoid action, and which substantially does not act to suppress the proliferation of vascular endothelial cells and substantially does act to suppress the proliferation of vascular smooth muscle cells (claims 1 and 4). Brown et al. also teaches the use wherein the injury is due to atherosclerosis. Brown et al. also further teaches inclusion of such medicaments in stents or the like in sustained release form in order to prevent vascular restenosis by means of intravascular stents (claim 5).

Brown et al. does not teach however the use of 4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)carbamoyl] benzoic acid.

Kagechika et al. teaches 4-[5,6,7,8-tetrahydro-5,5,8,8-tetramethyl-2-naphthalenyl)carbamoyl] benzoic acid or a salt thereof as a substance having retinoic activity. Kagachika et al. further states that Am80 is among the most active retinobenzoic acid.

It would be prima facie obvious to one skilled in the art at the time of the invention, to use Am80 as taught by Kagechika et al. as the medicament as taught by Brown et al. for preventing and/or treating vascular disease. A person skilled in the art would have been motivated to use Am80 as taught by Kagechika et al. having retinoic acid-like physiological activity as the retinoid in Brown et al.

Claim(s) 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al. as applied to claim 1-4, 6-8 and 12 above, and further in view of Murakami et al. (1999). Brown et al. teaches the use of medicament for preventing and/or treating vascular disease, wherein the medicaments include as an active

ingredient a substance which is selected from a set comprising retinoid and regulators of retinoid action, and which substantially does not act to suppress the proliferation of vascular endothelial cells and substantially does act to suppress the proliferation of vascular smooth muscle cells (claims 1 and 4). Brown et al. also teaches the use wherein the injury is due to atherosclerosis. Brown et al. also further teaches inclusion of such medicaments in stents or the like in sustained release form in order to prevent vascular restenosis by means of intravascular stents (claim 5).

Brown et al. does not teach however the use of 4-[[[3,5-bis(trimethylsilyl)phenyl]carbonyl]amino]benzoic acid or a salt thereof.

Murakami et al. teaches 4-[[[3,5-bis(trimethylsilyl)phenyl]carbonyl]amino]benzoic acid or a salt thereof as a retinoid acid with antiangiogenic activity and regulated retinoid action.

It would be prima facie obvious to one skilled in the art at the time of the invention, to use Tac-101 as taught by Murakami et al. as the medicament as taught by Brown et al. for preventing and/or treating vascular disease. A person skilled in the art would have been motivated to use Tac-101 as taught by Murakami et al. having retinoic acid-like physiological activity as the retinoid in Brown et al.

Conclusion

No claim is allowed

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANNETTE HOLLOMAN whose telephone number is (571) 270-5231. The examiner can normally be reached on Mon-Fri 730-500.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres can be reached on 571-272-0867 or Cecilia Tsang on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JANET L ANDRES/
Supervisory Patent Examiner, Art Unit 4131

/N. H./
Examiner, Art Unit 4131